The Pharmaceutical Education & Research Institute, Inc.

Biologics and Biosimilars: An Integrated Overview of Product Development

April 27 - 28, 2017 ✦ Fairfax, Virginia

Day One – Thursday, April 27, 2017 **Tab No.**

8:00 – 8:30 AM ***Registration and Continental Breakfast***

8:30 – 8:45 AM **PERI Welcome & Introduction of Course**
Jo Ann Zoul
Course Manager
Pharmaceutical Education & Research Institute, Inc. (PERI)

Paul Beninger, MD
Course Director
Director, MD/MBA Program, Tufts University School of Medicine
Boston, MA

8:45 – 9:45 AM **The History of Biologics** 1
Martin Green, PhD
Supervisory Toxicology
Division of Vaccines and Related Product Applications
CBER, FDA

- Scientific and Regulatory Distinctions Between Drugs and Biological Products
- History of the Events and Laws Governing Biological Product Regulation

9:45 – 10:45 AM **Regulatory Aspects of Biologics, Follow-on Biologics & Their Regulatory Pathway** 2
Gillian Woollett, MA, DPhil
V.P. FDA Regulatory Policy
Avalere Health

10:45 – 11:00 AM ***Morning Break***

11:00 – 12:00 AM **Preclinical Development of Biologics – A Scientific and Regulatory Perspective** 3
Christopher Ellis, Pharmacologist
Division of Anti-Viral Products
CDER, FDA

Properties of Biologics & Biosimilars – A Brief Overview
- Successfully Planning Preclinical Safety Studies for Biologics
- Immunogenicity and Preclinical Studies
- Strategy for Successful Preclinical Development

12:00 – 1:00 PM	***Lunch on your Own***	
1:00 – 2:00 PM	**Perspective on Pharm/Tox Assessment for Cell and Gene Therapy Products** ***Jinhua Lu, PhD*** Pharmacology/Toxicology Reviewer Office of Tissues and Advanced Therapies (OTAT) CBER, FDA • Definition of Cell & Gene Therapy • Potential Challenges in toxicology program design	4
2:00 – 3:00 PM	**Therapeutic Biologics** Orest Hurko, MD Senior Clinical Consultant, Rare Disease Unit Pfizer • Definition of Biologics • Biologics vs Small Drugs • Reorganization • Derailing Development During Clinical Trials • Impediments of Licensure & Approval of Major Supplements • TSE Issues	5
3:00 – 3:15 PM	***Afternoon Break***	
3:15 – 4:15 PM	**Translational Medicine in Biologics Discovery to Development** Chandrasekhar Natarajan Chief Scientific Officer ViNa Pharma Consultants, LLC. • Biomarkers for Stratification – Opportunities • Biomarkers Reflecting Pharmacodynamics – Relevance • Exploratory Clinical Studies – Challenges • Modeling Difficulties – Response Prediction	6

Day Two – Friday, April 28, 2017

8:00 – 8:30 AM	***Continental Breakfast***	
8:30 – 9:30 AM	**Overview of Clinical Trial Design** Orest Hurko, MD Senior Clinical Consult, Rare Disease Unit Pfizer • Characteristics of biologics in clinical development • Overview of study phases • Description of some study designs • Controls used in clinical studies	7

9:30 – 10:30 AM	**Clinical Strategies in Biologics Development** Orest Hurko, MD Senior Clinical Consult, Rare Disease Unit Pfizer • Adaptive Designs • Exploratory Clinical Studies • Orphan Diseases • Biomarkers and Accelerated Approval	8
10:30 – 10:45 AM	**Morning Break**	
10:45 – 11:45 AM	**Statistical Topics for Clinical Trials** Jay Horrow, MD, MS, FACC Executive Director, Global Clinical Development, Merck & Co. Professor of Anesthesiology & Perioperative Care Drexel University College of Medicine, Philadelphia, PA • When to Consult a Statistician • What Your Statistician Wants from You • Randomness, Bias, and other Annoyances	9
11:45 – 1:00 PM	***Lunch on your Own***	
1:00 – 2:00 PM	**Pharmacovigilance: The Basics** Paul R. Beninger, MD – Course Director • Why Safety? • Case Work-Up: Classical Activities • Risk Management: The New Paradigm	10
2:00 – 2:30 PM	**Summary Discussion: Questions and Answers** Paul R. Beninger, MD & Orest Hurko, MD	

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